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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,054	07/31/2003	Robert E. Richard	02-465	9964

27774 7590 08/12/2010

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,054	RICHARD ET AL.	
	Examiner	Art Unit	
	Brian-Yong S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 15-30* is/are pending in the application.

4a) Of the above claim(s) *15 and 19-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13,16-18 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner for the instant application has changed. The current examiner assigned to this application is Brian-Yong S. Kwon. Claims 1, 3-13, 16-18 and 30 are presented for examination.

2. Applicant's arguments with respect to 1, 3-13, 16-18 and 30 have been fully reconsidered during Pre-Appeal Brief Conference and are persuasive. Accordingly, the **finality of the rejection** mailed May 12, 2009 has been **withdrawn**.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Objections

3. Claims 7 is objected to for use of improper Markush claim language (see MPEP 2173.05(h). Suggest rewording of "selected from…and…" to "selected from the group consisting of…and…".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-13, 16-18 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, it is not clear what are the alternative species listed in Markush type language. It is not clear whether boundaries of the claimed homopolymers or copolymers must contain all of the recited species such as "polytetrafluorotheylene, collagen, cellulose, polyisobutylene, poly(2-methyl butane), and poly(2-methyl pentene" or alternatively selected from polytetrafluorotheylen, collagen, cellulose, polyisobutylene, poly(2-methyl butane) or poly(2-methyl pentene). Applicant is requested to clarify.

For the examination purpose, "a polymer selected from the group consisting of homopolymers and copolymers containing....and poly(2-methyl pentene)" is interpreted as a homopolymer or a copolymer containing polytetrafluorotheylene, collagen, cellulose, polyisobutylene, poly(2-methyl butane) or poly(2-methyl pentene).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3-13, 16-18 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. (US 2002/0107330), further in view of Li et al. (US 2003/0224033) and Dinh et al. (US 5571166). .

The claims 1, 3-13, 16-18 and 30 read on an medical device comprising a therapeutic agent and a polymer release region further comprising a homopolymer or a copolymer containing polytetrafluorotheylene, collagen, cellulose, polyisobutylene, poly(2-methyl butane) or poly(2-methyl pentene), wherein said polymeric release region is treated with a radiation dose of at least 100,000 rads that is effective to reduce the molecular weight of the polymer and substantially increase the cumulative release of said therapeutic agent in an amount of at least 10% subsequent to administration to a patient. Further limitations include "a radiation of dose of at least 1,000,000 rads" (claim 3); "said polymeric release region is a carrier region that comprises said therapeutic agent" (claim 4); "said polymeric release region is a barrier reegio" disposed over a therapeutic-agent-containing region..." (claim 5); "said polymeric release region is in the form of coating layer" (claim 6); "said implantable or insertable medical device is selected from a catheter, a guide wire…" (claim 7); "said implantable or insertable medical device is adapted for implantation…" (claim 8); "said therapeutic agent is selected from one or more of the group consisting of an anti-thrombotic agent…" (claim 9); "the cumulative release of

therapeutic agent is increase by an amount selected from 15% or more…" (claim 10); "the cumulative release of therapeutic agent is increased by an amount ranging from 25% to 100%..." (claim 11); "said polymer comprises polyisobutylene…" (claim 12); "said polymer comprises polyisobutylene and polystyrene…" (claim 13); "said polymer comprises polyisobutylene" (claim 16); "said polymer comprises polyisobutylene and polystyrene" (claim 17); "said polymer is a polystyrene-polyisobutylene-polystyrene triblock copolymer" (claim 18); and "said polymeric release region" treated with a radiation dose in the range of 1 Mrad to 10 M rad" (claim 30).

Pinchuk teaches a implantable or insertable medical device (e.g., catheters, guide wires, balloons, filters etc…) comprising (a) a biocompatible polymer or copolymer such as block copolymer (i.e.., a polystyrene-polyisobutylene-polystyrene triblock copolymer which shows advantage of resisting to cracking and other forms of degradation, their high tensile strength and having good biocompatibility) (b) a therapeutic agent (i.e., anti-thrombotic agent, an anti-proliferative agent, an anti-inflammatory agent, an anti-migratory agent...) wherein the block copolymer is loaded with the therapeutic agent; wherein the block copolymer is to form coatings over at least a portion of the medical device surfaces; wherein the therapeutic agent is released from the device or device portion after implantation; and wherein the medical device is adapted for implantation into the coronary vasculature or peripheral vascular system, espohagus, trachea, colon, biliary tract, urinary tract, prostate and brain (abstract; para. [0004]-[0005], [0010], [0015], [0017]-[0018], [0026], [0042]-[0043], [0059]-[0176], [0177], [0180-0183], [0190], [0220]; Examples). Particularly, Figure 1 of Pinchuk discloses the increase in the release rate of

the therapeutic agent (e.g., paclitaxel) from polystyrene-polyisobutylene-polystyrene copolymer coatings in respective relative amounts of the drug and copolymer increased.

Dinh and Li are being provided as a supplemental reference to demonstrate the routine knowledge in using radiation, approximately at 2.5-3.5Mrad, in sterlizing the final coated implantable or insertable medical device (column 11, lines 39-55 of Dinh'166; para. [0103-0104] of Li'033).

The teaching of Pinchuk mainly differs from the instant invention in the radiation treatment to the polymeric release region, namely a radiation dose of at least 100,000 rads. To incorporate such teaching into the teaching of Pinchuk, it would have been obvious in view of Ding and Li who teaches the routine knowledge in using radiation at 2.5Mrad in sterlizing the final coated implantable or insertable medical device.

As discussed above, one having ordinary skill in the art would have expected as taught by Ding and Li that the implantable or insertable medical devices are typically sterilized with radiation such as gamma or electron beam radiation at approximately 2.5Mrad. Furthermore, one having ordinary skill in the art would have recognized that the implantable or insertable medical device comprising (a) a biocompatible block copolymer (i.e.., a polystyrene-polyisobutylene-polystyrene triblock copolymer) (b) a therapeutic agent (i.e., anti-thrombotic agent, an anti-proliferative agent, an anti-inflammatory agent, an anti-migratory agent...) disclosed in Pinchuk would have required a sterilization process before final packaging. Thus, one having ordinary skill in the art would have been motivated to modify the teaching of Pinchk with the reasonable

expectation of success that the sterilization with radiation at approximately 2.5 Mrad would provide the sterilized final product.

With respect to the property of "reduce the molecular weight of the polymer", such property or property deems to be expected feature (inherent) to the referenced medical device when it is treated with the radiation at approximately 2.5 Mrad for sterilization process. Thus, the references in combination make obvious the instant invention.

With respect to the property of the specific increase of the cumulative release of therapeutic agent in patient or over the specific period of time recited in claims 1, 10-13 , such determination of the appropriate increase of the cumulative release of said therapeutic agent in patient or over period of time involving each of the above mentioned formulations or product is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed in Pinchuk (for example Figure 1; Example 5). One having ordinary skill in the art would have expected as taught by Pinchuk that the release rate can be varied by varying the relative amounts of drug and copolymer and be motivated to make such modification to maximize or optimize the release rates of the therapeutic agent.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also

Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 3-13, 16-18 and 30 provisionally rejected under the judicially created doctrine of double patenting over claims 1-23 of copending Application No.10/894400 or claims 1 and 4-23 of copending Application No.10/632,008. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

In response to above rejections, applicants, in their remarks of 14 December 2007, 17 October 2008, 30 January 2009 and 07 July 2009, have declined to discuss the merits but rather, have opted to address these provisional rejections at a future time when theses rejections only remain. Until such time, the rejection is considered proper and therefore, maintained.

7. Claims 1, 3-13, 16-18 and 30 are rejected under the judicially created doctrine of double patenting over claims 1-29 of U. S. Patent No. 7241455 (which was previous US Patent Application No. 10/409358) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

Response to Arguments

Applicant's argument in the response takes the position that "it is a basic tenet of polymer chemistry that crosslinking builds molecular weight…the present invention teaches the opposite, describing a polymer whose molecular weight is reduced by exposure to radiation".

This argument is not found persuasive. Although the methylene-containing polymers are crossedliked by radiation, the polymeric release regions of US'455 allows for inclusion of block copolymers (see claim 21). Since there is no indication in the patented claims that only the methylene-containing polymers in the polymeric release region are treated with radiation, the claims are construed to include the exposure of block copolymers containing region in the polymeric release region to radiation. This radiation treatment to the block copolymers would

(inherently) result in reducing the molecular weight of the polymer. The examiner determines that US'455 makes obvious the instant invention.

Thus, one having ordinary skill in the art, reading the entire context (column 2, lines 29; column 9, lines 54-56)-polyisobutylene-polystyrenes block copolymers such as SIBS is listed as only block copolymer- would have understood that the boundaries of the patented claims, especially claim 21, would encompass the inclusion of polyisobutylene-polystyrenes block copolymers such as SIBS that is treated with a radiation. scope of the patented claims overlaps with the instant invention. Thus, using the specification as "dictionary" in this ODP (obviousness-type double patenting) rejection analysis, the patented claims of US'455 makes obvious the instant invention.

Conclusion

8. No Claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614